DOCKET NO.: ISPH-0595USA

APPLICATION NUMBER:

10/559,647

FILING DATE:

07/31/2006

FIRST NAMED INVENTOR:

Rosanne M. Crooke

ART UNIT:

1635

**EXAMINER NAME:** 

**Amy Hudson Bowman** 

ATTORNEY DOCKET NUMBER:

ISPH-0595USA

TITLE:

MODULATION OF APOLIPOPROTEIN

(a) EXPRESSION

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## INFORMATION DISCLOSURE STATEMENT Under 37 C.F.R. §§ 1.56 and 1.97-98

SIR:

Pursuant to the provisions of 37 C.F.R. §§ 1.56 and 1.97-98, enclosed herewith is PTO Form PTO/SB/08A and PTO/SB/08B listing references for consideration by the Examiner.

This Information Disclosure Statement is being filed before the mailing date of a first office action on the merits, therefore it is believed that no fee is due. This application was filed after June 30, 2003. Therefore, pursuant to the waiver of the requirements under 37 C.F.R. § 1.98(a)(2)(i), copies of each U.S. Patent and each U.S. Patent Application Publication are not required to be submitted. Copies of any foreign patent documents and non-patent literature cited herein are enclosed.

Respectfully Submitted,

Frances R. Putkey, Ph.D.

Dated: April 11,2007

Registration No.: 57,257 Isis Pharmaceuticals, Inc.

1896 Rutherford Rd. Carlsbad, CA 92008 Phone: 760-603-2710

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Substitute for form 1449/PTO Complete if Known Application Number 10/559,647 INFORMATION DISCLOSURE Filing Date 07/31/2006 STATEMENT BY APPLICANT First Named Inventor Rosanne M. Crooke Art Unit 1635

(Use as many sheets as necessary)

(Use as many sheets as necessary)			necessary)	Examiner Name	Amy Hudson Bowman
Sheet	1	of	4	Attorney Docket Number	ISPH-0595USA

			U.S. PATENT	_	
Examiner Initials *	Cite No.1	Document Number  Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevan Passages or Relevant Figures Appear
	AA	US-5,721,138	02-24-1998	Lawn	rigares repeal
	AB	US-5,866,551	02-02-1999	Benoit et al.	
	AC	US-5,801,154	09-01-1998	Baracchini et al.	
	AD	US-6,008,344	12-28-1999	Bennett et al.	
	AE	US-6,080,580	06-27-2000	Baker et al.	
	AF	US-6,512,161	01-28-2003	Rouy et al.	
<del>-</del> -	ÅG	US-6,573,050	06-03-2003	Ben-David et al.	
	AH	US-6,613,567	09-02-2003	Bennett et al.	
	ΑI	US-6,809,193	10-26-2004	McKay et al.	
	AJ	ÚS-2003/0119766	06-26-2003	Crooke et al.	
	AK	US-2004/0242516	12-02-2004	Crooke et al.	
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	FOREIGN PATENT DOCUMENTS								
Evaminar	Cito	Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines, Where Relevant				
Initials*	Examiner Cite Initials* No.1	Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> ( <i>if known</i> )	Date MM-DD-YYYY	Applicant of Cited Document	Passages or Relevant Figures Appear	T <sup>6</sup>			
	AL	WO 96/09392 A1	03-28-1996	Ribozyme Pharm.	1				
	AM	WO 99/34016 A2	07-08-1999	Genena Ltd.					
	AN	WO 99/35241 A1	07-15-1999	Rhone-Poulenc					
	AO	WO 03/014307 A2	02-20-2003	Isis Pharma.					
	AP	WO 2005/000201 A2	01-06-2005	Isis Pharma.					

Examiner Signature	Date Considered	

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Substitute for form 1449/PTO Complete if Known Application Number 10/559,647 INFORMATION DISCLOSURE Filing Date 07/31/2006 STATEMENT BY APPLICANT First Named Inventor Rosanne M. Crooke Art Unit 1635 (Use as many sheets as necessary) Examiner Name Amy Hudson Bowman Sheet of Attorney Docket Number ISPH-0595USA

	<del>,</del>	NON PATENT LITERATURE DOCUMENTS	, <u>.</u>
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	AQ	AGRAWAL, S., "Antisense oligonucleotides: towards clinical trials," <i>TIBTECH</i> (1996) 14:376-387.	
	AR	ANDERSON, L. et al., "A comparison of selected mRNA and protein abundances in human liver," <i>Electrophoresis</i> (1997) 18:533-537.	
	AS	BRAASCH, D. A. et al., "Novel Antisense and Peptide Nucleic Acid Strategies for Controlling Gene Expression," <i>Biochem.</i> (2002) 41(14):4503-4510.	
_	AT	BRANCH, A. D., "A good antisense molecule is hard to find," TIBS (1998) 23:45-50.	
	AU	CALLOW, M. J. et al., "Expression of human apolipoprotein B and assembly of lipoprotein (a) in transgenic mice," <i>Proc. Natl. Acad. Sci. USA</i> (1994) 91:2130-2134.	
	AV	CHIESA, G. et al., "Reconstitution of Lipoprotein (a) by Infusion of Human Low Density Lipoprotein into Transgenic Mice Expressing Human Apolipoprotein (a)," J. Biol. Chem. (1992) 267(34):24369-24374.	
	AW	CHIN, A., "On Preparation and Utilization of Isolated and Purified Oligonucleotides," Katherine R. Everett Law Library of the University of North Carolina, March 14, 2002.	
	ΑX	DEVERRE, JR. et al., "A competitive enzyme hybridization assay for plasma determination of phosphodiester and phosphorothioate antisense oligonucleotides," <i>Nucleic Acids Res.</i> (1997) 25(18):3584-3589.	
	AY	DIAS, N. et al., "Potential roles of antisense oligonucleotides in cancer therapy. The example of bcl-2 antisense oligonucleotides." <i>Eur. J. Pharm. Biopharm.</i> (2002) 54:263-269.	
	AZ	FRANK, S. et al., "Advenovirus-mediated apo(a)-antisense-RNA expression efficiently inhibits apo(a) synthesis in vitro and in vivo," <i>Gene Therapy</i> (2001) 8:425-430.	
	ВА	FRANK, S. et al., "The apolipoprotein(a) gene resides on human chromosome 6q26-27, in close proximity to the homologous gene for plasminogen," <i>Hum. Genet.</i> (1988) 79(4):352-356.	
	ВВ	FRITZ, H. et al., "Cationic Polystyrene Nanoparticles: Preparation and Characterization of a Model Drug Carrier System for Antisense Oligonucleotides," <i>J. Colloid Interface Sci.</i> (1997) 195:272-288.	
	вс	GEWIRTZ, A. M. et al., "Facilitating oligonucleotide delivery: Helping antisense deliver on its promise," <i>Proc. Natl. Acad. Sci. USA</i> (1996) 93:3161-3163.	

Examiner	Date	
Signature	Considered	

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Substitute	for form 1449/PTO				Complete if Known
INIEO	ON A TION	DIO	OL OOUDE	Application Number	10/559,647
			CLOSURE	Filing Date	07/31/2006
STAT	STATEMENT BY APPLICANT			First Named Inventor	Rosanne M. Crooke
				Art Unit	1635
	(Use as many she	ets as	necessary)	Examiner Name	Amy Hudson Bowman
Sheet	3	of	4	Attorney Docket Number	ISPH-0595USA

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	BD	GRAINGER, D. J. et al., "Activation of transforming growth factor-β is inhibited in transgenic apolipoprotein(a) mice," <i>Nature</i> (1994) 370:460-462.	
	BE	GREEN, D. W. et al., "Antisense Oligonucleotides: An Evolving Technology for the Modulation of Gene Expression in Human Disease," J. Am. Coll. Surg. (2000) 191:93-105.	
	BF	HAJJAR, K. A. et al., "The Role of Lipoprotein(a) in Atherogenesis and Thrombosis," Annu. Rev. Med. (1996) 47:423-442.	
	BG	JEN, KY. et al., "Suppression of Gene Expression by Targeted Disruption of Messenger RNA: Available Options and Current Strategies," Stem Cells (2000) 18:307-319.	
	ВН	KATAN, M. B. et al., "Characteristics of Human Hypo- and Hyperresponders to Dietary Cholesterol," <i>Am. J. Epidemiology</i> (1987) 125(3):387-399.	
	ВІ	KOSTNER, K. M. et al., "Lipoprotein(a): still an enigma?" Current Opinion in Lipidology (2002) 13:391-396.	
	BJ	LAWN, R. M. et al., "Atherogenesis in transgenic mice expressing human apolipoprotein(a)," <i>Nature</i> (1992) 360:670-672.	
	вк	MCLEAN, J. W. et al., "cDNA sequence of human apolipoprotein(a) is homologous to plasminogen," <i>Nature</i> (1987) 330:132-137.	
	BL	MILLIGAN, J. F. et al., "Current Concepts in Antisense Drug Design," J. Med. Chem. (1993) 36(14):1923-1927.	
	ВМ	MORISHITA, R. et al., "Novel Therapeutic Strategy for Atherosclerosis – Ribozyme Oligonucleotides Against Apolipoprotein(a) Selectively Inhibit Apolipoprotein(a) But Not Plasminogen Gene Expression," <i>Circulation</i> (1998) 98:1898-1904.	
	BN	NOWAK-GÖTTL, U. et al., "Lipoprotein (a): Its Role in Childhood Thromboembolism," Pediatrics (1997) 99(6):1-3.	_
	во	OHMICHI, T. et al., "The virtues of self-binding: high sequence specificity for RNA cleavage by self-processed hammerhead ribozymes," <i>Nucleic Acids Res.</i> (2000) 28(3):776-783.	
	BP	OPALINSKA, J. B. et al., "Nucleic-Acid Therapeutics: Basic Principles and Recent Applications," Nature Reviews Drug Discovery (2002) 1:503-514.	

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Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

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INITO	DRACTION!	DIC	CLACURE	Application Number	10/559,647
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	BQ	PROSNYAK, M. I. et al., "Substitution of 2-Aminoadenine and 5-Methylcytosine for Adenine and Cytosine in Hybridization Probes Increases the Sensitivity of DNA Fingerprinting," <i>Genomics</i> (1994) 21:490-494.	
	BR	RAINWATER, D. L. et al., "Lipoprotein Lp(a): Effects of Allelic Variation at the LPA Locus," J. Exp. Zoology (1998) 282:54-61.	
	BS	SANDKAMP, M. et al., "Lipoprotein(a) is an Independent Risk Factor for Myocardial Infarction at a Young Age," Clin. Chem. (1990) 36(1):20-23.	
	ВТ	SEED, M. et al., "Relation of Serum Lipoprotein(a) Concentration and Apolipoprotein(a) Phenotype to Coronary Heart Disease in Patients with Familial Hypercholesterolemia," New Engl. J. Med. (1990) 322:1494-1499.	
	BU	SKERRA, A., "Phosphorothioate primers improve the amplification of DNA sequences by DNA polymerase with proofreading activity," <i>Nucleic Acids Res.</i> (1992) 20(14):3551-3554.	
	BV	TAMM, I. et al., "Antisense therapy in oncology: new hope for an old idea?" The Lancet (2001) 358:489-497.	
	BW	VESSBY, B. et al., "Diverging Effects of Cholestyramine on Apolipoprotein B and Lipoprotein Lp(a)," <i>Atherosclerosis</i> (1982) 44:61-71.	
	вх	WEINTRAUB, H. M., "Antisense RNA and DNA," Scientific American (1990) 40-46.	
	BY	YANG, Y. et al., "Transforming Growth Factor-β1 Inhibits Human Keratinocyte Proliferation by Upregulation of a rEceptor-Type Tyrosine Phosphatase R-PTP-κ Gene Expression," <i>Biochem. Biophys. Res. Commun.</i> (1996) 228:807-812.	

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